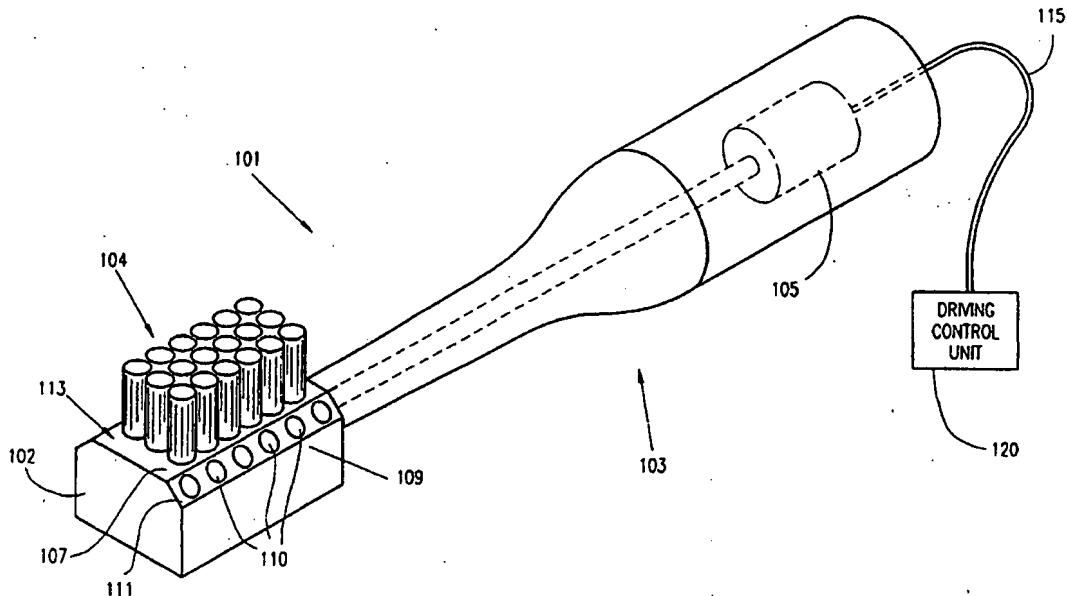




INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61C 1/00, 3/00, A46B 9/04		A1	(11) International Publication Number: WO 95/10243
			(43) International Publication Date: 20 April 1995 (20.04.95)
(21) International Application Number: PCT/US94/11401		(81) Designated States: AM, AT, AU, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, JP, KE, KG, KP, KR, KZ, LK, LR, LT, LU, LV, MD, MG, MN, MW, NL, NO, NZ, PL, PT, RO, RU, SD, SE, SI, SK, TJ, TT, UA, US, UZ, VN, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG), ARIPO patent (KE, MW, SD, SZ).	
(22) International Filing Date: 5 October 1994 (05.10.94)			
(30) Priority Data: 107248 11 October 1993 (11.10.93) IL			
(71) Applicants (for all designated States except US): BIO BRIGHT CORPORATION [US/US]; 333 East 38th Street, New York, NY 10016 (US). BIO BRUSH INDUSTRIES LTD. [IL/IL]; Kibbutz Ruhama, 79180 Israel (IL). AMRON, LTD. [IL/IL]; 98 Yigal Allon Street, 61027 Tel Aviv (IL).		Published <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>	
(72) Inventors; and			
(75) Inventors/Applicants (for US only): MENDES, Emanuel [IL/IL]; 10 Haoranim Street, Neve Oz, 49213 Petach Tikva (IL). MAIRON, Omri [IL/IL]; Kibbutz Ruhama, 79180 Israel (IL).			
(74) Agents: GALLOWAY, Peter, D. et al.; Ladas & Parry, 26 West 61st Street, New York, NY 10023 (US).			

(54) Title: APPARATUS FOR TREATMENT OF THE ORAL CAVITY



(57) Abstract

This disclosure presents an invention for providing an apparatus and method for oral hygiene and treatment within the oral cavity. The apparatus includes an elongate member (103) having a head portion (102) formed on one end thereof and a plurality of light emitting diodes (LEDs) (110) mounted on the head (102) for emitting radiation in a preselected bandwidth centered at a wavelength suitable for treatment in the oral cavity. The method thereof includes exposing the preselected area of the oral cavity to radiation from the apparatus.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	GB	United Kingdom	MR	Mauritania
AU	Australia	GE	Georgia	MW	Malawi
BB	Barbados	GN	Guinea	NE	Niger
BE	Belgium	GR	Greece	NL	Netherlands
BF	Burkina Faso	HU	Hungary	NO	Norway
BG	Bulgaria	IE	Ireland	NZ	New Zealand
BJ	Benin	IT	Italy	PL	Poland
BR	Brazil	JP	Japan	PT	Portugal
BY	Belarus	KE	Kenya	RO	Romania
CA	Canada	KG	Kyrgyzstan	RU	Russian Federation
CF	Central African Republic	KP	Democratic People's Republic of Korea	SD	Sudan
CG	Congo	KR	Republic of Korea	SE	Sweden
CH	Switzerland	KZ	Kazakhstan	SI	Slovenia
CI	Côte d'Ivoire	LI	Liechtenstein	SK	Slovakia
CM	Cameroon	LK	Sri Lanka	SN	Senegal
CN	China	LU	Luxembourg	TD	Chad
CS	Czechoslovakia	LV	Latvia	TG	Togo
CZ	Czech Republic	MC	Monaco	TJ	Tajikistan
DE	Germany	MD	Republic of Moldova	TT	Trinidad and Tobago
DK	Denmark	MG	Madagascar	UA	Ukraine
ES	Spain	ML	Mali	US	United States of America
FI	Finland	MN	Mongolia	UZ	Uzbekistan
FR	France			VN	Viet Nam
GA	Gabon				

- 1 -

APPARATUS FOR TREATMENT OF THE ORAL CAVITY
FIELD OF THE INVENTION

5 The present invention relates to
apparatus for dental hygiene and therapy in the
oral cavity.

BACKGROUND OF THE INVENTION

10 Light therapy is known for treating a
variety of patients' complaints and ailments. A
device suitable for administering light therapy
is disclosed in United States Patent 4,930,504
to Diamantopoulos et al. Diamantopoulos et al.
hypothesize that their device may be used for
example to treat inflammations, wounds, burns,
chronic ulcerations including diabetic ulcers,
15 deficient circulation, pain, nerve regeneration,
eczema shingles, infection, scars, acne, bone
fractures, muscle and ligament injuries,
arthritis, osteo-arthritis, rheumatiodal
arthritis, skin grafts, gingival irritation,
20 oral ulcers, dental pain and swelling,
cellulitis, stretch marks, skin tone, alopecia
areata, trigeminal neuralgia, herpes, zosten,
sciata, cervical erosions and other conditions.

25 Diamantopoulos et al. describe the use
of an array of substantially monochromatic
radiation sources of a plurality of wavelengths,
preferably, of at least three different wave

- 2 -

lengths. The radiation sources are arranged such that radiation of at least two different wavelengths passes directly or indirectly through a single point located within the treated tissue.

Use of LED's in administering light therapy for the treatment of certain ailments and complaints is disclosed in published UK application GB 2212010A.

The oral cavity is a sensitive area of the body. People normally eat every day, and teeth and gums must be cleaned to prevent dental disease such as dental cavities and gum disease. At present, oral disease prevention is normally accomplished through regular oral hygiene, including, particularly, the use of the ubiquitous toothbrush to keep teeth clean. Effective use of the toothbrush, however, requires proper brushing action.

Electric toothbrushes provide automated movement of a toothbrush head. This is usually accomplished by having the toothbrush head associated with a vibrating unit which causes the head, and hence the bristles mounted thereon, to vibrate, and thus produces effective brushing action. Electric toothbrushes have proven to be convenient.

The toothbrush, however, is not an appropriate device for treating eruptions and lesions of the skin within the oral cavity. Moreover, despite good oral hygiene practice, other ailments can produce pain and suffering within the oral cavity, such as gingival irritation, oral ulcers, and dental pain and swelling.

SUMMARY OF THE INVENTION

The present invention seeks to provide

- 3 -

apparatus and a method for oral hygiene and treatment within the oral cavity.

There is thus provided in accordance with a preferred embodiment of the present invention apparatus for brushing teeth and providing treatment including prophylactic treatment for possibly one or more of gingival irritation, oral ulcers, dental pain and swelling among other diseases (hereinafter referred to as "oral ailments") by illumination, including at least one light emitting diodes (LEDs), each diode including apparatus for emitting non-coherent narrow band light in a preselected bandwidth centered at a wavelength suitable for prophylactic treatment of oral ailments.

Further in accordance with a preferred embodiment of the present invention, the apparatus includes means for concentrating the light of at least one LED and for projecting the light to an oral zone, preferably the gums, for biostimulative treatment thereof, wherein preferentially the light emitted by each of the plurality of diodes has substantially the same wavelength.

Further in accordance with another aspect of the present invention, the plurality of LEDs is arranged on the head of a toothbrush, which is preferably an electric toothbrush. The plurality of LEDs preferably includes one or more circular or linear arrays of LEDs preferably arranged in an area outside the bristle area on the head of the toothbrush.

In an alternative embodiment of the present invention, LEDs are arranged in a waterproof enclosure resembling a toothbrush lacking bristles.

- 4 -

Still further in accordance with a preferred embodiment of the present invention, the preselected bandwidth comprises a narrow red light bandwidth centered at a wavelength of approximately 660 nm.

Additionally in accordance with a preferred embodiment of the present invention, a continuous wave LED driver is provided for driving the LEDs in a continuous wave (CW) mode.

Still further in accordance with a preferred embodiment of the present invention, each of the LEDs emits a cone of light, and the LEDs are configured and arranged such that at least one linear array of LEDs forms an aggregation of cones of light whose projection onto an area within the oral cavity illuminates a desired zone for prophylactic treatment, due to the partial overlapping of substantially parallel, offsetting, circular spots of light projected by the LEDs of the linear array. In a preferred embodiment of the present invention, the projection from the linear array is particularly suited for illuminating a region of the gums, while brushing teeth.

In an alternative embodiment of the present invention, a plurality of LEDs providing therapeutic illumination are situated on the head of an elongate member (not having bristles as in a toothbrush). The elongate member is ergonomically designed to irradiate "hard to reach" areas of the oral cavity.

There is also provided in accordance with a preferred embodiment of the present invention, a method for oral hygiene and prophylactic treatment of the oral cavity comprising the steps of exposing an oral area, preferably the gums, to radiation from at least

- 5 -

one LED, while brushing one's teeth, or as a regular part of oral hygiene.

BRIEF DESCRIPTION OF THE DRAWINGS

5 The present invention will be understood and appreciated more fully from the following detailed description, taken in conjunction with the following drawings in which:

10 Figure 1 is a perspective view of oral hygiene and prophylactic treatment apparatus, constructed and operative in accordance with a preferred embodiment of the present invention;

 Figure 2 is a top view schematic illustration of the apparatus of Figure 1;

15 Figure 3 is a side view schematic illustration of the apparatus of Figure 1, showing a plurality of cones of light emanating from an LED array, in accordance with a preferred embodiment of the invention;

20 Figure 4 depicts an angular displacement of the cones of light of Figure 3 from the normal to the plane that bristles are mounted on;

 Figure 5 depicts an illumination pattern projected by the LED array of Figure 3;

25 Figure 6 depicts a preferred and normal use of the apparatus of Figures 1-5 by a person;

30 Figure 7 is a simplified block diagram of the circuitry useful for the operation of the apparatus of Figures 1 - 6 and Figure 9;

 Figure 8 is a schematic illustration of the circuitry useful for the operation of an LED array, in accordance with a preferred
35 embodiment of the invention;

 Figure 9 is a schematic diagram of prophylactic treatment apparatus, constructed

- 6 -

and operative with an alternative embodiment of the present invention; and

Figure 10 is a schematic illustration of circuitry useful for the operation of the apparatus depicted in Figure 9.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

Referring to Figure 1, there is shown oral prophylactic treatment apparatus including a toothbrush 101 comprising a head 102, a handle 103, and bristles 104 which are mounted on a bristle area 107 of head 102. Preferably, the oral prophylactic treatment apparatus also comprises a vibrator unit 105 for vibrating head 102, and hence bristles 104 mounted thereon, to provide automated brushing action.

In a preferred embodiment of the invention as shown in Figure 1, a linear array 109 of LEDs 110 is mounted on toothbrush head 102 on a strip 111 located outside the bristle area 107 of toothbrush head 102. When connected to a driving control unit 120, subsequently described in greater detail, LEDs 110 function as a radiation source to provide illumination for prophylactic treatment and/or relief of oral ailments, such as gingival irritation, oral ulcers, and dental pain and swelling. It should be noted that LEDs 110 are preferably mounted on toothbrush head 102 such that linear array 109 lies on a plane angled away from the bristle plane 113 of toothbrush head 102 as shown in Figure 4.

In an alternative embodiment of the invention (not shown), LEDs 110 may be mounted within bristle area 107 such that bristles 104 surround LEDs 110.

Referring additionally to Figure 4, each of the LEDs 110, when appropriately driven,

- 7 -

projects a cone of light 401 whose illumination pattern is preferably circular 402. The right perpendicular bisector 403 of cone of light 401 is preferentially angled at an angle 404 (alpha) from the normal to bristle plane 113, and preferentially perpendicular to the plane of linear array 109. The aggregation of cones of light 401 from the LEDs 110 within linear array 109 preferentially forms an elongated illumination pattern that is substantially rectangular as depicted in Figure 5.

The length 502 of the rectangular illumination pattern is slightly longer than the length of linear array 109. The width 503 of the rectangular illumination pattern is dependent upon the distance "D" along the bisector 403 from the LED array 110 to the illuminated area, and the angular spread (beta) 406 of the cone of light 401. Thus, the width "w" (503) of the substantially rectangular illumination pattern is defined by the relationship

$$w = 2 * D * \text{sqrt}(\sec^2(\text{beta}/2) - 1).$$

The intensity of light on the illuminated area varies in accordance with the strength of the light output of each LED 110 and the concentration of LEDs 110 on toothbrush head 102.

It will be appreciated that the particular arrangement of LEDs 110 corresponding to the angular displacement 404 of LEDs 110 in the present preferred embodiment of the invention, as shown in Figures 1 - 5, is particularly suited for illuminating the dental and gum region of the oral cavity while brushing one's teeth, as depicted in Figure 6.

Referring additionally to Figure 7,

- 8 -

there is shown a compact light source 701 (corresponding to linear array 109 located on strip 111 of toothbrush head 102) and an associated control unit 702 (corresponding to driving control unit 120) which preferably features a CW (continuous wave) mode of operation. Light source 701 comprises a plurality of LEDs 704 which receive power via a driver circuit 706. Preferably, each of the LEDs 704 emits light of substantially the same frequency. The control unit 702 contains a power supply 707 and a timer 710 which can be a standard timer circuit provided with "set time" switches as normally used in electric clocks, and whose function is to disable the control circuit 702 after a preset time has elapsed.

An amplitude and/or duty cycle variation circuit 712 provides a voltage signal with variable amplitude and/or duty cycle which is fed to the driver 706 of the light source 701. Thus, the light source 701 emits light continuously with a magnitude determined by amplitude/duty cycle variation circuit 712.

Additionally, Figure 8 shows a preferred embodiment for the driving of LEDs 110 in detail. LEDs 110 are arranged in the form of an LED matrix 820 comprising a plurality of parallel branches, each of which contains a predetermined number of LEDs 110 connected in series. Thus, in Figure 8, three LEDs 822a, 823a, and 824a are connected in series and constitute part of a parallel branch 825 of diode matrix 820. The voltage flowing through this branch is limited by means of a series resistor 826a, and the resulting branch is connected between a high voltage D.C. rail 828 and low voltage D.C. rail 830. Thus, one

- 9 -

terminal of the series connected voltage-limiting resistor is connected to the high voltage rail 828, whilst the cathode of LED 824a is connected to the low voltage rail 830. The circuitry of all other branches of the LED matrix 820 is identical to the circuitry, thus far described, of branch 825.

According to an alternative embodiment, the LEDs may be driven by a current source.

The operation of the electrical circuit is as follows. The amplitude and/or duty variation circuit 712 operates to provide a voltage with variable amplitude and/or duty cycle between high voltage supply rail 828 and low voltage rail 830. Thus, by varying the setting of the amplitude/duty cycle variation circuit 812, the overall current flowing through LED matrix 820 can be varied, thereby varying the light intensity of light source 701.

A preferred power level is between 10 and 30 mW/cm² and, more preferably, approximately 20 mW/cm². The exact wavelength of the illumination is confined within a relatively narrow bandwidth (+/- 25 nm) and its central value may be predetermined by suitable selection of LEDs in LED matrix 820. It is believed that red light, centered at a frequency of 660 nm, is particularly suitable for prophylactic treatment of human tissue. The average intensity of the emitted illumination may be varied, and the treatment time may be preset by means of timer 710, which preferably includes an integral timer circuit.

Thus, the invention affords low cost apparatus for oral hygiene and prophylactic treatment in the oral cavity, by providing a

- 10 -

toothbrush bearing a source of non-coherent radiation, preferably generated in CW mode, which is projected into the oral cavity, particularly onto the gums. Moreover,
5 preventive treatment, the efficacy of which is dependent upon regular use of the prophylactic illumination provided by the present invention, is enhanced by the unobtrusive daily ritual of brushing one's teeth.

10 It will be appreciated that the particular features of the methods and apparatus shown and described herein may be employed separately or in combination in any suitable manner so as to enhance efficacy of treatment.

15 An alternative embodiment of the present invention places two LEDs 110 at the end of apparatus resembling a toothbrush, minus the bristles, as depicted in Figure 9.

Referring to Figure 9, a head 900
20 attached to a neck 902 is screwably connected via a threaded sleeve 913 and a threaded receptor 914 to a handle 904. Preferably, head 900 is ergonomically shaped for easy placement within the oral cavity. The relative thinness
25 of neck 902 allows a person to close one's teeth while head 900 is within the oral cavity. A relatively thick handle 904 is provided for ease of holding the apparatus and for containing batteries 906 disposed within. Preferably, the
30 apparatus is constructed out of soft and non-abrasive material suitable for use in the mouth, such as an acetale plastic, Delrin. The apparatus is essentially waterproof as head 900 is composed of a single piece and LEDs 110,
35 disposed within head 900, have openings which are sealed. Furthermore, an O-ring 908 ensures the waterproofness of the battery housing,

- 11 -

namely handle 904. LEDs 110 are activated by rotating handle 904, in a switchable manner well known in the art.

5 LEDs 110 are situated at the end of head 900 to allow for farther reach to the ends of the gums compared to a toothbrush. LEDs 110 are placed within a channel 916. Channels 916 project cones of LED light which preferably overlap to form a relatively intense spot of
10 light for projecting onto the gums. Channel 918 is used to store circuit components such as resistors.

It is believed that the apparatus depicted in Figure 9 to be useful for the
15 therapeutic treatment of gum diseases and other oral cavity disorders.

Figure 10 depicts a circuit diagram useful for powering LEDs 110 in the arrangement depicted in Figure 9.

20 It will be appreciated by persons skilled in the art that the present invention is not limited by what has been particularly shown and described hereinabove. Rather the scope of the present invention is defined only by the
25 claims which follow.

- 12 -

C L A I M S

1. Apparatus for oral hygiene and prophylactic treatment of the oral cavity comprising:
 - 5 a toothbrush including a head with bristles; and
 - a plurality of light emitting diodes (LEDs) mounted on the head and emitting radiation in a pre-selected bandwidth centered
 - 10 at a wavelength suitable for prophylactic treatment in the oral cavity.
2. Apparatus for treatment of the oral cavity comprising:
 - 15 an elongate member having a head portion formed on one end thereof; and
 - a plurality of light emitting diodes (LEDs) mounted on the head for emitting radiation in a preselected bandwidth centered at a wavelength suitable for treatment in the oral
 - 20 cavity.
3. Apparatus according to claim 1 or claim 2, wherein the radiation emitted by the plurality of LEDs is projected onto desired zones in the oral cavity for biostimulative
- 25 treatment thereof.
4. Apparatus according to claim 1, 2, or 3, wherein each of said LEDs emits non-coherent radiation.
5. Apparatus according to any of the
- 30 preceding claims, wherein each of said LEDs emits radiation of substantially the same wavelength and there are no other LEDs having other wavelengths.
6. Apparatus according to any of the
- 35 preceding claims wherein the plurality of LEDs emit a plurality of cones of light which form a projection shape including an aggregation of

- 13 -

partially overlapping illuminated spots.

7. Apparatus according to claim 5, wherein said plurality of LEDs comprises a linear array of LEDs.

5 8. Apparatus according to any of the preceding claims, wherein the pre-determined bandwidth comprises a narrow red light bandwidth.

9. Apparatus according to claim 8, wherein the narrow red light bandwidth is centered at a wavelength of approximately 660 nm.

10 10. Apparatus according to any of the preceding claims, and further comprising a continuous wave LED driver for driving the plurality of LEDs in a continuous wave (CW) mode.

11. Apparatus according to claim 1 and any of claims 3 - 10, wherein the projection shape of illuminated radiation is substantially rectangular.

12. Apparatus according to any of claims 1 and 3 - 11, wherein said toothbrush is an electric toothbrush.

25 13. Apparatus according to claim 14, wherein the elongated member and associated head is waterproof.

14. A method for prophylactic treatment of the oral cavity comprising the steps of:

30 providing apparatus for prophylactic treatment of the oral cavity according to any of claims 1 - 15; and

exposing a preselected area of the oral cavity to radiation from the apparatus.

35 15. A method for oral hygiene and prophylactic treatment of the oral cavity comprising the steps of:

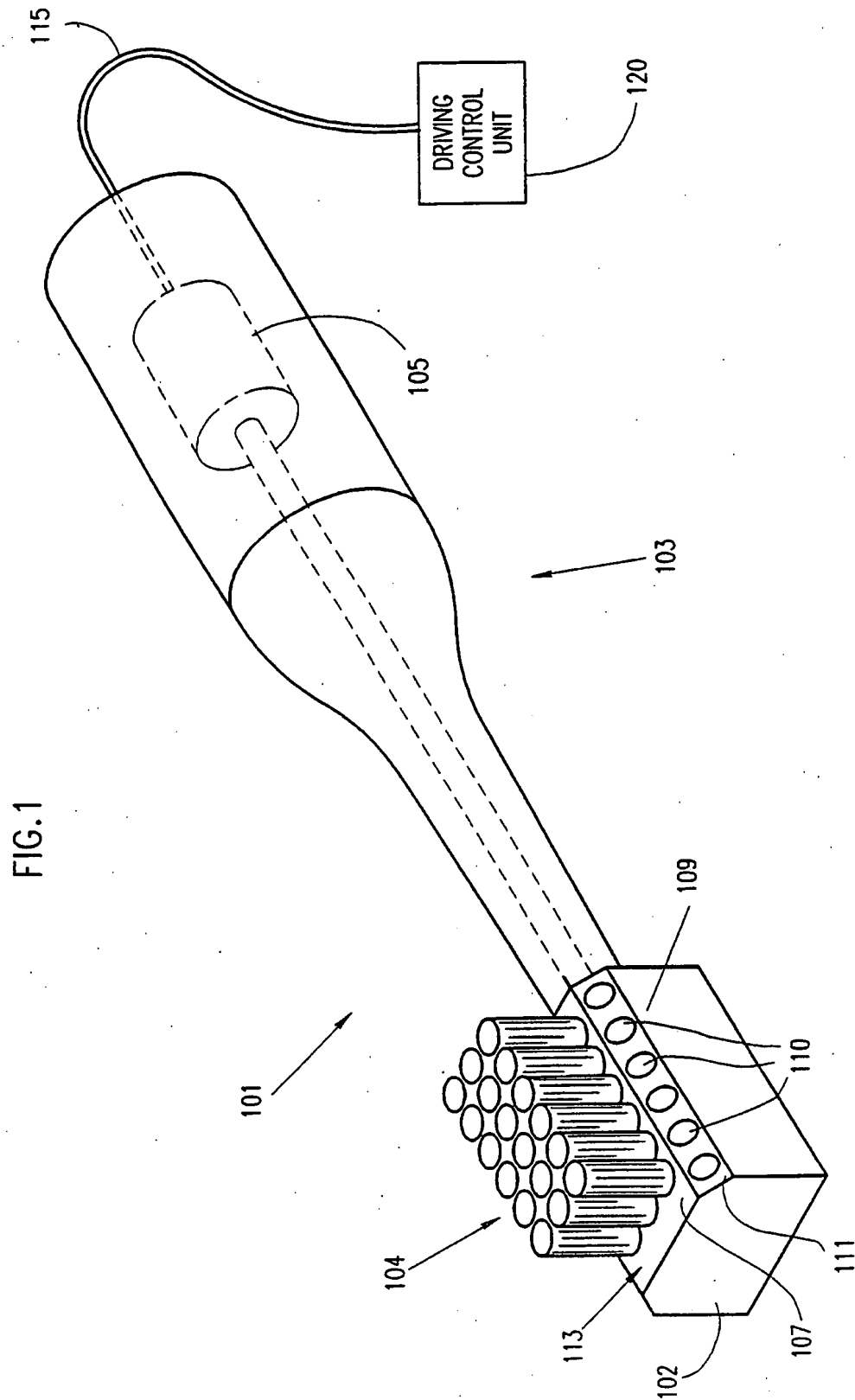
- 14 -

providing apparatus for prophylactic
treatment of the oral cavity according to claim
1 and any of claims 3 - 13; and

brushing one's teeth,

5 wherein preselected regions of the
oral cavity are irradiated by radiation from
LEDs.

1/6



2/6

FIG.2

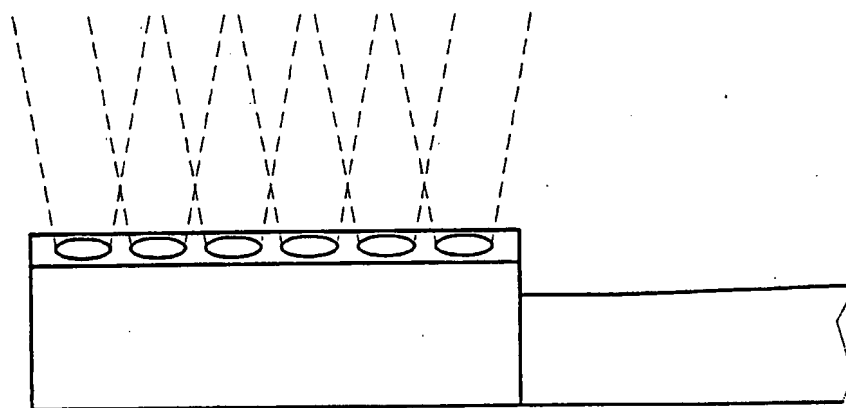
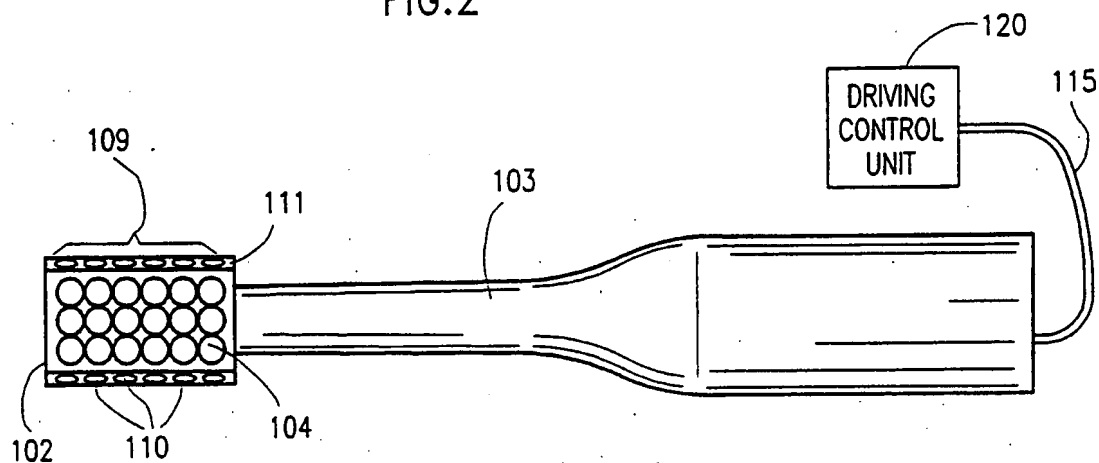


FIG.3

3/6

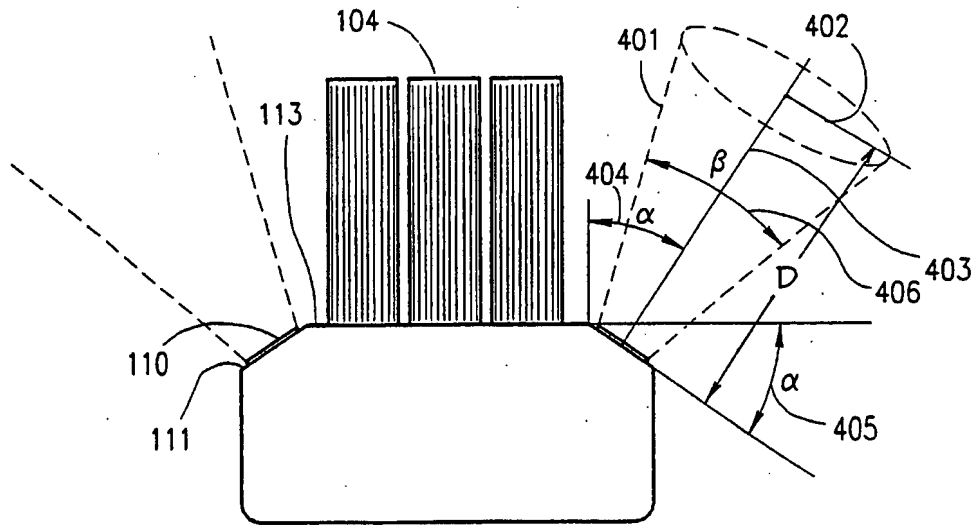


FIG. 4

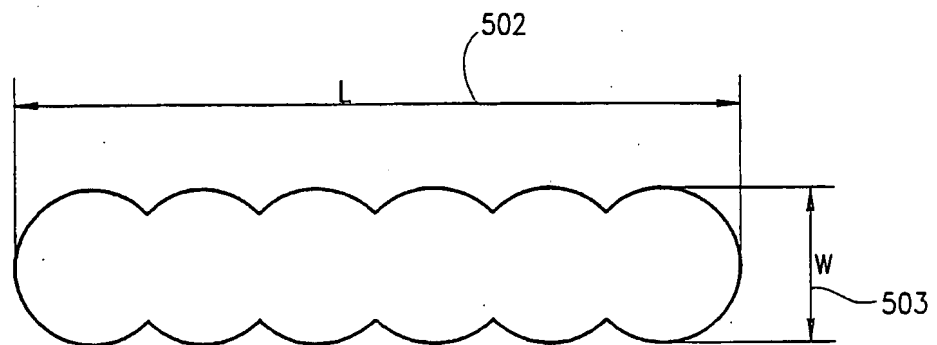


FIG. 5

4/6

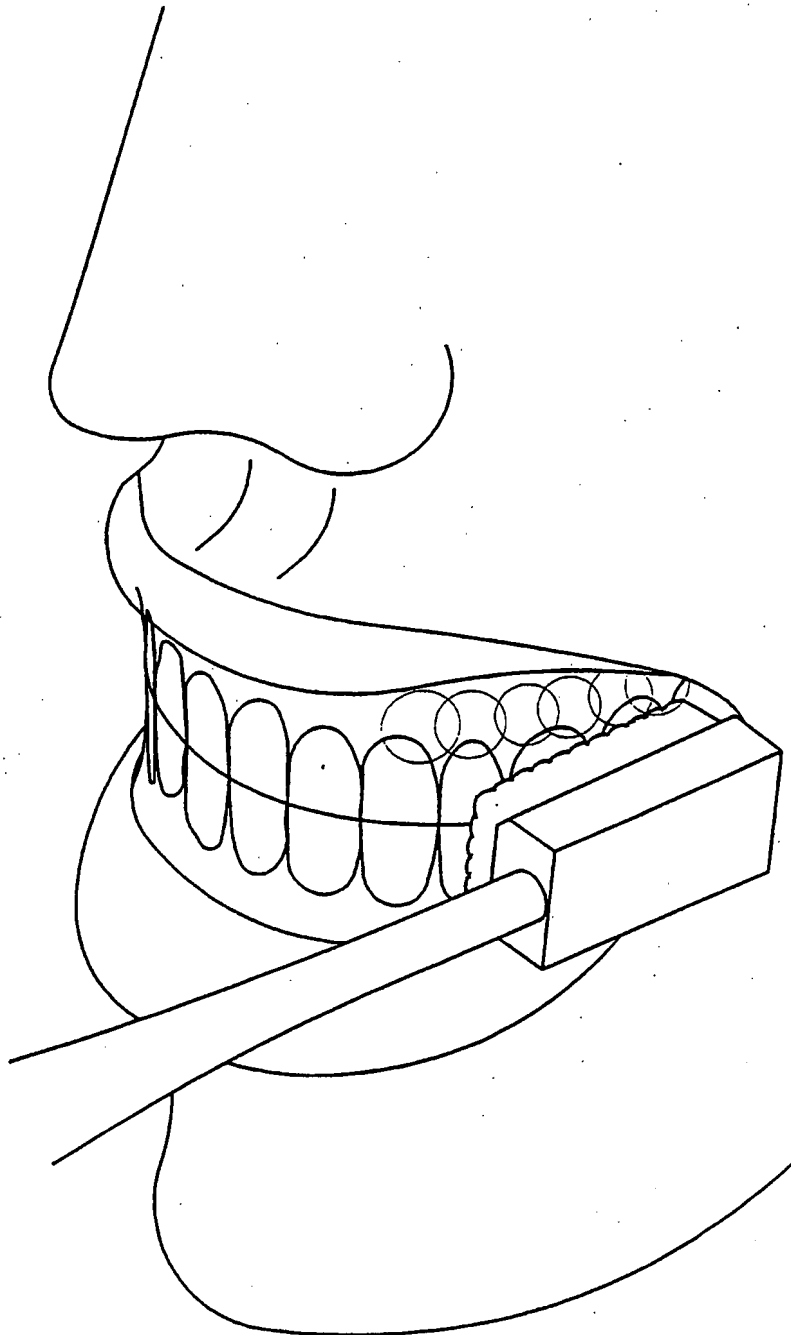


FIG.6

5/6

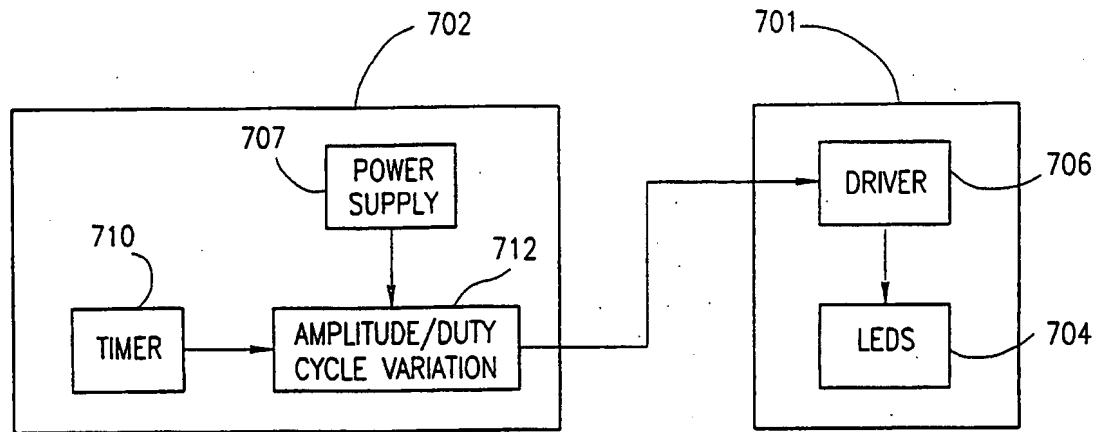


FIG. 7

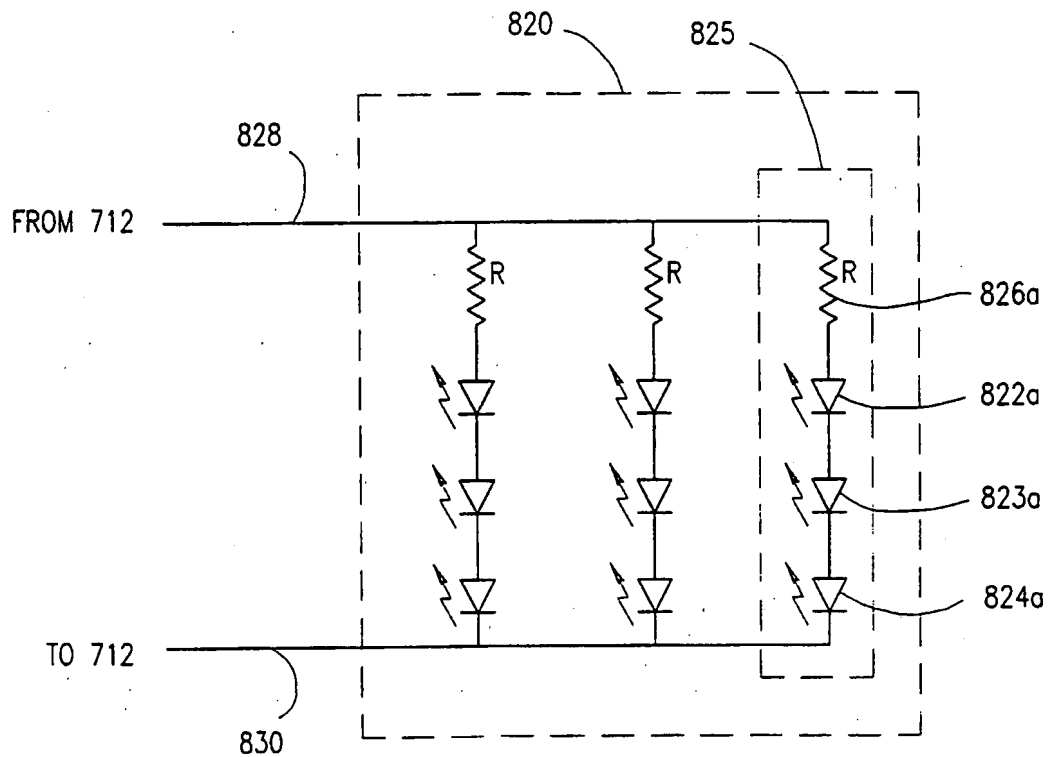


FIG. 8

6/6

FIG.9

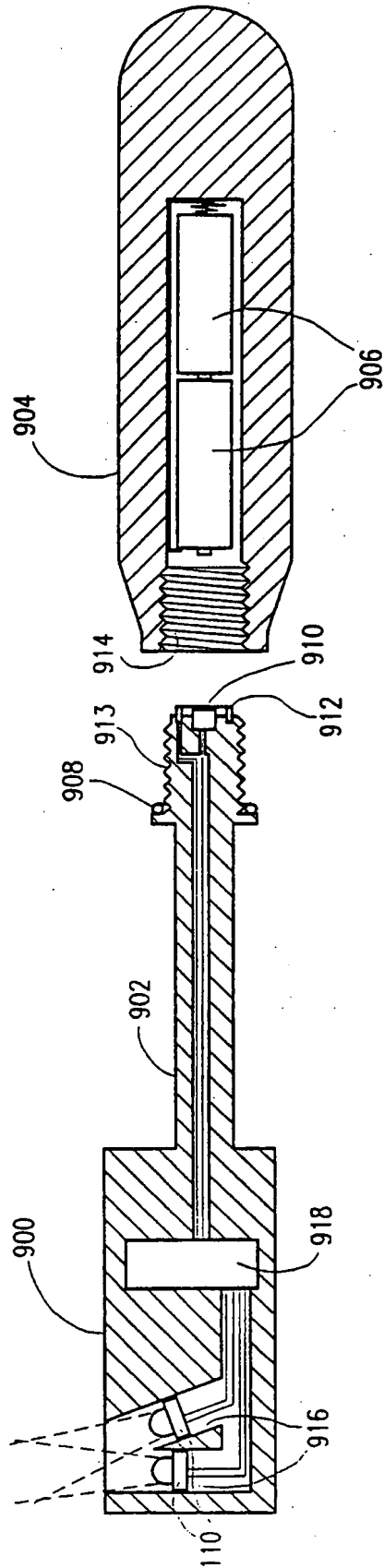
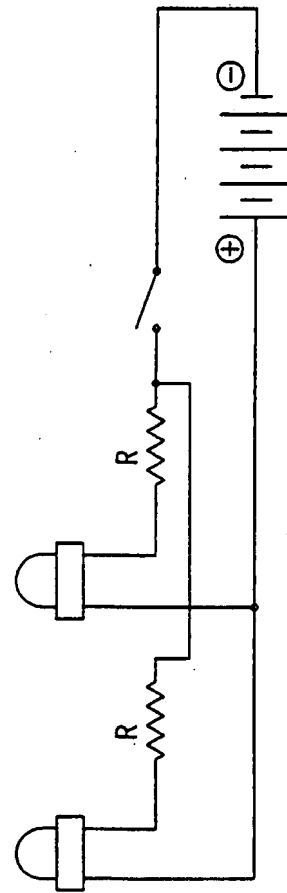


FIG.10



INTERNATIONAL SEARCH REPORT

International application No.

PCT/US94/11401

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61C 1/00, 3/00; A46B 9/04

US CL :433/29; 15/167.1

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 433/29, 215, 216, 229; 15/167.1, 167.2; 362/109, 804

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US, A, 5,030,090 (Maeda et al.) 09 July 1991, see column 1, lines 5-22, column 2, line 40 to column 3, line 24.	1-15
Y	US, A, 3,261,978 (Brenman) 19 July 1966, see Figs. 2 and 3; and column 2, lines 18-24.	1-15
Y	JP, A, 3,251,207 (Saeki) 08 November 1991, see abstract and Figs.	6, 8-15
A, P	US, A, 5,306,143 (Levy) 26 April 1994, see entire document.	1-15
A	US, A, 4,779,173 (Carr et al.) 18 October 1988, see entire document.	1-15
A	US, A, 5,160,194 (Feldman) 03 November 1992, see entire document.	1-15



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents:	*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
A document defining the general state of the art which is not considered to be part of particular relevance	*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
E earlier document published on or after the international filing date	*Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*G* document member of the same patent family
O document referring to an oral disclosure, use, exhibition or other means	
P document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

24 JANUARY 1995

Date of mailing of the international search report

10 MAR 1995

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Authorized officer

CARY O'CONNOR

Facsimile No. (703) 305-3230

Telephone No. (703) 305-0858

Form PCT/ISA/210 (second sheet)(July 1992)*